

APR 10 2008

TRANSMITTAL LETTER  
(General - Patent Pending)

Docket No.  
002.00270 (DUNBW/P30950US)

In Re Application Of: Hardie et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/565,058	July 16, 2004	S. Swope	Not Assigned	1652	

Title: METHODS FOR USE OF AN LKB1/STRAD7M025 COMPLEX

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

**Response to Written Restriction Requirement (6 pages)**

**Self-addressed, stamped postcard for acknowledging receipt of the enclosed materials**

in the above identified application.

No additional fee is required.

A check in the amount of \_\_\_\_\_ is attached.

The Director is hereby authorized to charge and credit Deposit Account No. **50-0772** as described below.

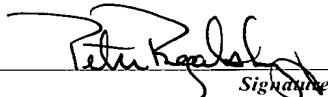
Charge the amount of \_\_\_\_\_

Credit any overpayment.

Charge any additional fee required.

Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

  
Peter Rogalskyj  
Signature

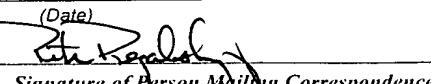
Dated: April 8, 2008

Peter Rogalskyj, Esq.  
Reg. No. 38,601  
The Law Office of Peter Rogalskyj  
P.O. Box 44  
Livonia, New York 14487-0044  
Tel.: 585-346-1004  
Fax: 585-346-1001

cc:

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

**4-8-08**

  
(Date)  
Peter Rogalskyj  
Signature of Person Mailing Correspondence

Peter Rogalskyj  
Typed or Printed Name of Person Mailing Correspondence



002.00270 (DUNBW/P30950US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Hardie et al. )  
Serial No.: 10/565,058 )  
Filed: July 16, 2004 ) Examiner: S. Swope  
For: METHODS FOR USE OF AN ) Art Unit: 1652  
LKB1/STRAD7M025 COMPLEX )  
\_\_\_\_\_  
)

**RESPONSE TO WRITTEN RESTRICTION REQUIREMENT**

Mail Stop Amendment  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

This paper is being filed in response to the March 13, 2008, written restriction requirement in the above-captioned application.

Prior to addressing substantive aspects of the restriction requirement, applicants will first address certain preliminary matters raised in the March 13, 2008, written restriction requirement.

As a first preliminary matter, the outstanding written restriction requirement states that the original claims set of January 17, 2006, included claims 1-39; and that the amended claims set filed January 17, 2006, does not list claims 36-39. In this regard, applicants note that two

amendments were made to the claims of the International Application under PCT Article 19, and that these amendments (i.e., those made under PCT Article 19) were communicated by the International Bureau. (See item 7, particularly item 7(b) of applicants' Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Submission Under 35 U.S.C. 371, as filed on January 17, 2006.) The amended claims (set forth in the Preliminary Amendment filed January 17, 2006) show the changes relative to the claims set forth in the second (i.e., last) Article 19 amendment. The second Article 19 amendment contained a total of 35 claims. For this reason the Preliminary Amendment filed January 17, 2006, did not list claims 36-39. If this approach to amending the claims is unacceptable, it is requested that the Examiner contact applicants' undersigned attorney by telephone (585-346-1004) so that a claims set in acceptable form can be submitted.

As a second preliminary matter, the outstanding written restriction requirement states that, if applicants wish to perfect their priority claim to foreign applications UK 0316725.1 and UK 0330078.7, these applications should be filed. In response, applicants note that certified copies of UK 0316725.1 and UK 0330078.7 were provided to the International Bureau in the counterpart PCT application and that no further submission is necessary to perfect applicants' priority claims.

As a third preliminary matter, the outstanding written restriction requirement suggests that applicants' point to those documents cited in the Information Disclosure Statement ("IDS") that are most significant to the elected invention. Since it is not clear how the U.S. Patent and Trademark Office ("PTO") intends apply the references cited in the IDS or what other references the PTO may uncover, it is not possible for applicants to identify those documents that are most significant to the elected invention.

As a fourth and last preliminary matter, the outstanding written restriction requirement advises that all citations are to include an author, date, and, where relevant, journal name, volume, and page numbers. It is not clear as to which citations fail to comply with these requirements. It is requested that the PTO point to which citations are deficient and identify how the alleged deficiency can be remedied. Applicants note that certain citations (particularly GenBank citations) do not include author, date, journal name, volume, and page numbers. However the format of these citations (as used in the IDSs in this case) is the same the format commonly employed by the PTO when it cites GenBank documents (e.g., on a PTO-892 form). If the outstanding written restriction requirement is referring to applicants' GenBank citations, it is requested that the Examiner provide applicants' undersigned attorney with a format that should be used for such citations.

Having addressed the preliminary matters raised in the March 13, 2008, written restriction requirement,

applicants turn now to the substance of the restriction requirement.

In response to the March 13, 2008, written restriction requirement, applicants hereby elect, with traverse, the claims of Group II (i.e., claims 3-5 and 16). Applicants' reasons for traversing the written restriction requirement are set forth below.

In addressing the propriety of the restriction requirement, the PTO states that the inventions listed as Groups I-XI(A) - (CC) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features. More particularly, the PTO asserts that (i) the technical feature linking Groups I-XI(A) - (CC) appears to be that they all relate to the LKB1-mediated pathway; (ii) the LKB1-mediated pathway is known in the art; and (iii) Fryer et al., J. Biol. Chem., 277(28):25226-25232 (2002) ("Fryer") teaches a method for identifying AMPK inhibitors, which anticipates claim 29.

Applicants submit that the PTO's conclusions with regard to Fryer appear to be in error. More particularly, claim 29 (which the PTO asserts is anticipated by Fryer) requires comparing the effect of the test compound on the activation of the AMPK by a preparation according to claim 3 with the effect of metformin or phenformin. Claim 3 relates to a purified preparation comprising LKB1, STRAD, and recombinant M025 expressed from a recombinant nucleic acid. There is no mention of recombinant M025 in Fryer. For at

least this reason, the PTO is wrong to consider that claim 29 is anticipated by Fryer and is therefore wrong to raise a lack of unity objection.

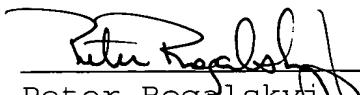
Moreover, applicants submit that it is inappropriate to impose a restriction requirement between the Group II claims and the claims of Groups I(A) - (B) and III-XI(C) - (CC) because the invention of Group II and those of Groups I(A) - (B) and III-XI(C) - (CC) are related to one another and would necessarily require common areas of search and consideration (see, MPEP § 808.02). Therefore, to conserve applicants' resources as well as those of the U.S. Patent and Trademark Office, applicants believe that the requirement for restriction between the invention of Group II and those of Groups I(A) - (B) and III-XI(C) - (CC) is improper in this case and should be reconsidered and withdrawn.

As a final matter, applicants note that the written restriction requirement may oversimplify or otherwise mischaracterize the subject matter to which at least some of the various groups are drawn. However, since such oversimplifications and mischaracterizations do not appear to affect the propriety of the requirement for restriction, applicants do not believe that further comment is required at this time, except to note that applicants' silence should not be construed as applicants' agreement with the written restriction requirement's characterization of the claims.

In view of the foregoing, it is submitted that the restriction requirement should be reconsidered and withdrawn and that all claims should be substantively examined in the present application. Should any issues exist which can

usefully be discussed by telephone, the Examiner is invited to contact applicants' undersigned attorney at 585-346-1004.

Dated: April 8, 2008

  
Peter Rogalsky  
Reg. No. 38,601

The Law Office of Peter Rogalsky  
P.O. Box 44  
Livonia, New York 14487-0044  
Tel: 585-346-1004  
Fax: 585-346-1001

**Certificate of Mailing - 37 CFR 1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

4-8-08

Date

Peter Rogalsky